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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,429	11/15/1999	CHRISTOPHER POWER	3045.00004	1631

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EXAMINER

EPPS, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 03/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/439,429

Applicant(s)

POWER ET AL.

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 5-6, and 9-12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, and those claims dependent thereon, claims 6, and claims 9-12, recite "an exon targeting a sequence which flanks at least one splice site said targeting thereby regulating expression of TNF- $\alpha$ ", this phrase is vague and indefinite since it is unclear which "exon" or "splice site" Applicants are referring to, particularly since the claim does not specifically recite what the target sequence is. Additionally, it is unclear if Applicant's claimed antisense oligodeoxynucleotide is intended to inhibit human tumor necrosis factor alpha (TNF- $\alpha$ ) mRNA expression or protein activity (wherein the antisense oligodeoxynucleotide functions as an aptamer). Moreover, if Applicant intends for the claimed antisense oligodeoxynucleotide to function as an inhibitor of TNF- $\alpha$  mRNA expression, it would be necessary for the claim to recite that the antisense oligodeoxynucleotide specifically targets (for example is complementary to, or specifically hybridizes to) TNF- $\alpha$  mRNA.

3. Claims 3-4, 7-10 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the expression of TNF-alpha *in vitro*, does not reasonably provide enablement for modulating, which includes for enhancing and inhibiting, the expression of TNF-alpha, *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

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commensurate in scope with these claims, for the reasons of record set forth in the Official Action mailed 11-02-2000.

Applicant's arguments filed 4-26-2001 have been fully considered but they are not persuasive. Applicants have not specifically addressed the arguments set forth in the Official Action mailed 11-02-2000. Applicants have merely duplicated the same arguments set forth in the correspondence received 8-15-2000.

4. Claim 5 remains rejected under 35 U.S.C. 102(e) as being anticipated by Nyce et al., for the reasons of record set forth in the Official Action mailed 11-02-2000.

Applicant's arguments filed 4-26-2001 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that although the Nyce et al. reference discloses antisense molecules targeting the adenosine A1 receptor, this reference does not mention "targeting intron-exon junctions for other genes such as tumor necrosis factor alpha." Contrary to Applicants assertions, the Nyce et al. reference clearly teach antisense oligonucleotides targeted human tumor necrosis factor alpha (col. 3, lines 24-25), and further states that the antisense oligonucleotides of their invention are preferably directed to an mRNA region of its target sequence containing a junction between intron and exon. Furthermore, Nyce et al. state that the antisense may either entirely overlies the junction or may be sufficiently close to the junction to inhibit splicing out of the intervening exon (col. 4, lines 55-65).

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
March 20, 2002

  
JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
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